UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/147,405	04/01/1999	BENGT GUSS	REF/GUSS/P33	1676

7590 08/06/2002

BACON & THOMAS
625 SLATERS LANE 4TH FLOOR
ALEXANDRIA, VA 223141176

EXAMINER
DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
1645	26

DATE MAILED: 08/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/147,405	Guss et al.
Examiner	**Art Unit**
S. Devi, Ph.D.	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 25, 2002* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above, claim(s) *2-24 and 26-29* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 25, and 30-32* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

RESPONSE TO THE AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 05/29/2002 (paper no. 25) in response to the non-final Office Action mailed 05/23/02 (paper no. 24), which amendment has been entered.

Status of Claims

2) Claims 1 and 25 have been amended via the amendment filed 05/29/2002.

New claims 30-32 have been added via the amendment filed 05/29/2002.

Claims 1-32 are pending.

Claims 1, 25 and 30-32 are under examination.

Prior Citation of Title 35 Sections

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Withdrawn

5) The rejection of claim 1 made in paragraph 8(a) of Office Action mailed 05/29/02 (paper no. 25) under 35 § U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

6) The rejection of claim 25 made in paragraph 8(b) of Office Action mailed 05/29/02 (paper no. 25) under 35 § U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

Specification

7) It is noted that the instant specification lacks antecedence or descriptive support for "SEQ ID NO: 11"; SEQ ID NO: 12", SEQ ID NO: 13" and "SEQ ID N:" 15".

The specification is objected to as failing to provide proper antecedent basis for the

claimed subject matter. See 37 C.F.R 1.75(d)(1) and M.P.E.P § 608.01(o). Correction of the following is required: The recitation "SEQ ID NO: 11" in the new claims 31 and 32 lacks antecedent basis in the specification. If the amino acid sequence depicted on pages 19-21 of the specification represents the instantly recited "SEQ ID NO: 11", then Applicants should consider providing antecedent basis for the recitation, i.e., amending the text at the bottom of page 21 by inserting the recitation 'SEQ ID NO: 11'.

Rejection(s) Maintained

8) The rejection of claims 1 and 25 made in paragraph 10 of Office Action mailed 05/29/02 (paper no. 25) under are rejected under 35 § U.S.C. 102(b) as being anticipated by the patent DE 3583987 A1, is maintained for reasons set forth therein. Applicants have advanced no arguments with regard to this rejection.

9) The rejection of claims 1 and 25 made in paragraph 10 of Office Action mailed 05/29/02 (paper no. 25) are rejected under 35 § U.S.C. 102(b) as being anticipated by Fiedler *et al.* (EP 350810 A or B), is maintained for reasons set forth therein and herebelow.

Applicants contend that Fiedler's epidermidin is isolated from *Staphylococcus epidermidis* by adsorption on styrene/acrylic based co-polymer. Applicants state that the instantly claimed protein has no 'significant' plastic binding activity as seen in Table 2. Applicants assert that the Office is not correct in assuming that the prior art polypeptide would have an inherent fibrinogen binding activity. Applicants provide a reference from *Infect. Immun.* 2666-2673, June 1998 and state that not all clinical isolates of *Staphylococcus epidermidis* contained fibrinogen-binding activity. Yet Applicants acknowledge that as many as 40 out of 43 clinical isolates of *Staphylococcus epidermidis* have fibrinogen-binding activity.

Applicants' arguments have been carefully considered, but are non-persuasive. Instant claims, as currently drafted, do not define the polypeptide structurally. The claimed protein does not exclude epidermidin. Since the claimed protein is not identified by one or more structural limitations, it encompasses epidermidin or any other purified protein of *Staphylococcus epidermidis*. Instant claims contain a functional limitation without reciting sufficient structure. In the instant case, the only structural limitation that needs to be met by a prior art purified

protein is that it must be of *Staphylococcus epidermidis* origin. The functional limitation, on which the prior art reference is silent, is considered as an inherent property of the prior art protein. Where the only difference between claimed product and the prior art product is recited in the functional language, i.e., by what it does rather than what it is, it is incumbent upon Applicants, when challenged by the USPTO, to demonstrate that the prior art product does not actually possess those characteristics. Whether or not the prior art protein is isolated by absorption on styrene is irrelevant, since the instant claims are not drawn to a method of isolating the protein. Even if instant claims were presented in the form of product-by-process claims by reciting specific method steps used to obtain the claimed protein, Fiedler would still qualify as anticipatory art. A product does not have to be made by the same process in order to be the same product, because a product is a product, no matter how it is claimed. When claims are presented as product-by-process claims, Applicants should show that the alleged differences in the process inherently result in a product that is structurally different from the product of the prior art.

With regard to the no 'significant' plastic binding activity of the protein, it is noted that the feature upon which Applicants rely is not a part of the currently rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993)*. The rejection stands.

10) The rejection of claims 1 and 25 made in paragraph 10 of Office Action mailed 05/29/02 (paper no. 25) under 35 § U.S.C. 102(e) maintained for reasons set forth therein and herebelow. 02(e) as being anticipated by Katz *et al.* (US 6,107,068), or Alborn *et al.* (US 5,587,307), is maintained for reasons set forth therein and herebelow.

Applicants contend that Katz *et al.* or Alborn *et al.* were filed on 02 July 1997 and 24 December 1996 and therefore, neither of these patents destroy the novelty of the present invention. Applicants state that Katz's protein is a coenzyme A disulfide reductase whereas Alborn's protein is involved in the formation of a pentaglycine bridge in the cell wall of the bacterium. Applicants state that neither of these references disclose any fibrinogen-binding activity.

Applicants' arguments have been carefully considered, but are non-persuasive. The

rejection is made under 35 § U.S.C. 102(e) as opposed to 35 § U.S.C. 102(b). The Katz patent '098 has an effective filing date of 22 December 1995 and the Alborn patent '307 has an effective filing date of 30 April 1993. Both patents qualify as prior art under 35 § U.S.C. 102(e). Instant claims, as currently drafted, do not define the protein structurally. The claimed protein does not exclude a coenzyme or another protein. Since the claimed protein is not identified by one or more structural limitations, it encompasses Katz's or Alborn's protein or any other purified polypeptide of *Staphylococcus epidermidis*. Instant claims contain a functional limitation without reciting sufficient structure. In the instant case, the only structural limitation that needs to be met by a prior art purified protein or polypeptide is that it must be of *Staphylococcus epidermidis* origin. The functional limitation, on which the prior art references are silent, is considered as an inherent property of the prior art polypeptide. Where the only difference between claimed product and the prior art product is recited in the functional language, i.e., by what it does rather than what it is, it is incumbent upon Applicants, when challenged by the USPTO, to demonstrate that the prior art product does not actually possess those characteristics. Whether or not the prior art protein is isolated by absorption on styrene is irrelevant, since the instant claims are not drawn to a method of isolating the polypeptide. Even if instant claims were presented in the form of product-by-process claims by reciting specific method steps used to obtain the claimed protein, Katz or Alborn would still qualify as anticipatory art. A product does not have to be made by the same process in order to be the same product, because a product is a product, no matter how it is claimed. When claims are presented as product-by-process claims, Applicants should show that the alleged differences in the process inherently result in a product that is structurally different from the product of the prior art.

New Rejection(s)

Applicants are asked to note the following new rejection(s) made in this Office. The new rejections are necessitated by Applicants' amendments and/or the submission of new claims.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

11) Claims 25, 30 and 32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) For clarity and in order to claim the subject matter distinctly, it is suggested that Applicants delete the recitation "having fibrinogen binding activity" in line 2 of claim 25 and claim 30 since this recitation is already encompassed by the product of the base claim 1.

(b) Claim 32, which depends from claim 30, is also rejected as being indefinite because of the problem identified above in the base claim.

Rejection(s) under 35 U.S.C. § 112, First Paragraph

12) Claims 1, 25 and 30-32 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 25, as amended, and new claims 30 and 31 include the recitation: "polypeptide fragment of the protein having fibrinogen binding activity". There is no descriptive support in the instant specification for a "polypeptide fragment" and for such a fragment "having fibrinogen binding activity". Therefore, the above-identified new limitation in the claim(s) is considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the newly added limitation(s), or to remove the new matter from the claim(s).

Rejection(s) under 35 U.S.C. § 102

13) Claims 1, 25 and 31 are rejected under 35 U.S.C. § 102(b) as being anticipated by McDevitt *et al.* (*Mol. Microbiol.* 11: 237-248, 1994).

It is noted that the instant specification in the paragraph bridging pages 10 and 11 describes the instantly claimed protein to be having sequence homology to the art-known fibrinogen binding protein (clumping factor) of *S. aureus*. This part of the specification describes the existence of sequence homology between the two proteins in the N- and C-terminal parts, the cell membrane spanning domain, the repetitive R region, and the non-repetitive

fibrinogen-binding A domain.

The term 'vaccine' in this rejection is viewed as the intended use of the product and is not given any patentable weight.

McDevitt *et al.* teach a staphylococcal fibrinogen binding protein comprising a fragment of the instantly claimed protein of the amino acid sequence, SEQ ID NO: 11. See Figure 7 McDevitt *et al.* A sequence search performed in the Office shows that McDevitt's protein comprises several contiguous stretches (i.e., fragments) of sequence identity with Applicants' SEQ ID NO: 11. The prior art fragments, YTFTDYV and IKVYK, show 100% sequence identity and both are from the fibrinogen-binding non-repetitive A region of the protein. See Figure 7 McDevitt *et al.* Since the prior art protein fragments from the A region, irrespective of their origin, are structurally 100% identical to the instantly claimed fragments, these fragments are expected to inherently have the same function(s) as that of the instantly claimed fragments, i.e., fibrinogen binding function.

Claims 1, 25 and 31 are anticipated by McDevitt *et al.*

Rejection(s) under 35 U.S.C. § 103

14) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a)** A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person. having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

15) Claims 1 and 30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fiedler

et al. (EP 350810 A or B, already of record), or McDevitt *et al.* (*Mol. Microbiol.* 11: 237-248, 1994) in view of Marston *et al.* (*In*: *Methods in Enzymology, Guide to Protein Purification.* (Ed) MP Deutscher. vol. 182, section 20, pages 264-276, 1991).

The teachings of McDevitt *et al.* are explained above, and the teachings of Fiedler *et al.* are explained in paragraph 10 of the Office Action mailed 01/25/02, which are silent on whether their protein or fragment is produced as a fusion protein.

However, the expression of a polypeptide or fragment thereof as a fusion polypeptide is well known and routinely practiced in the art of immunology/microbiology. For instance, Marston *et al.* teach the construction of polypeptides by gene fusion for the purpose of facilitating efficient purification (see pages 275 and 176).

It would have *prima facie* been obvious to one skilled in the art at the time the invention was made to express Fiedler's or McDevitt's fibrinogen binding protein or polypeptide fragment as a fusion polypeptide using the art known techniques to produce the instant invention with a reasonable expectation of success. Given the routine teaching of Marston that expression of a polypeptide in the form of a fusion polypeptide facilitates purification, a skilled artisan would have been motivated to produce the instant invention for the expected benefit of facilitating the efficient purification of Fiedler's or McDevitt's protein.

Claims 1 and 30 are *prima facie* obvious over the prior art of record.

Relevant Prior Art

16) The prior art made of record and not relied upon in any of the rejections is considered pertinent to Applicants' disclosure:

- Usui (*Zbl. Bakt. Hyg. A* 262: 287-297, 1986) teaches a purified fibrinogen binding protein or polypeptide of a coagulase negative *Staphylococcus aureus* and its amino acid contents (see abstract; Table 1; Figure 2; and 'Discussion').

Remarks

17) Claims 1, 25 and 30-32 stand rejected.

18) The Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

20) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

August, 2002

S. DEVI, PH.D.
PRIMARY EXAMINER